K012533

AUG 2 2 2001

August 1, 2001

Subject: Summary of Safety and Effectiveness Information for the OSI Medical Dolphin Stand-Alone Pulse Oximeter and Accessories.
Proprietary: OSI Medical Dolphin Stand-Alone Pulse Oximeter, Model No. 2100 and Accessories.
Common: Oximeter.
Classification: Oximeter Class II – 21 CFR 870.2700 – 74 DQA

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 1992.

The OSI Medical Dolphin Pulse Oximeter and Accessories is substantially equivalent to the following currently marketed device(s):

- OSI Medical Dolphin Stand-Alone Pulse Oximeter, Model No. 2100 and Accessories #K002036.

The OSI Medical Dolphin Pulse Oximeter and Accessories is a portable stand-alone device, connecting cable, and oximetry sensor(s) to noninvasively calculate the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate.

The monitor consists of a screen that displays the pulse plethysmographic waveform, the pulse rate, SpO_2 value, the high and low SpO_2 and pulse rate alarm limits, alarms, trends and status messages. It contains the electronic hardware and software that receives and calculates the signals from the LEDs within the sensor to determine the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate, and provide for the connection to the connecting cable.

The OSI Medical Dolphin Pulse Oximeter is available in one configuration as a portable stand-alone oximeter that is 10 cm / 3.94 inches high, 27.5 cm / 10.83 inches wide, 25 cm / 9.84 inches deep and weighs about 4 kg / 8.8 lbs. The unit is powered either with a voltage input of 100-240 Vac, 50-60 Hz or with a sealed lead-acid battery with an operating time of approximately 4 hours based upon 2 Ampere hour battery (200mA OEM Module, 300mA System Module) and a charge time of about 4.5 hours to 80% capacity.

The extension cable connects between the monitor and oximetry sensor(s) and transfers LED drive power and the calibration drive to the oximetry sensor from the monitor and the monitor receives the detector signal from the oximetry sensor.

The extension cable is available in one configuration and is approximately 8 feet / 2.44m in length, and the sensor(s) are approximately 18 inches / 45.72 cm in length.

The sensor(s) measure light absorption of blood from two light emitting diodes (LED's). Oxygen saturated blood absorbs light differently as compared to unsaturated blood. The amount of light absorbed by the blood is used to calculate the ratio of oxygenated hemoglobin to total hemoglobin in arterial blood.

The oximetry sensor is available in a disposable or reusable configuration, and with one configuration for the extension cable (8 feet).

The OSI Medical Dolphin Stand-Alone Pulse Oximeter, Model No. 2100 and Accessories have been designed to comply with the following standards:

1. CSA C22.2 No. 601.1
2. IEC 601-1, Part 1 and Amendments 1 and 2
3. IEC 601-1-1, Part 1
4. IEC 601-1-2, Part 1
5. ISO 9919: 1992
6. EN 865: 1997
7. FDA Guidance Document for Pulse Oximeters: 9/7/1992
8. ASTM 1415:1992, and Draft 10.1
9. UL2601-1: Second Edition, 1997
10. IEC 6068-2-6
11. IEC 6068-2-27
12. IEC 6068-2-64
13. ISTA Procedure 2A

The OSI Medical Dolphin Stand-Alone Pulse Oximeter with disposable sensors is substantially equivalent in design concepts, technologies and materials to the OSI Medical Dolphin Stand-Alone Pulse Oximeter, with reusable sensors. Additional testing has been performed for the disposable sensors including biocompatibility and performance validation which has been included in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2001

Mr. Jon Werner
QA Manager
OSI Medical, Inc.
13801 McCormick Drive
Tampa, FL 33626

Re: K012533
OSI Medical Digital Dolphin Disposable Optical Sensor, Model 510
Regulation Number: 870.2700
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: August 3, 2001
Received: August 6, 2001

Dear Mr. Werner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012533

Device Name: OSI Medical Dolphin Stand-Alone Pulse Oximeter, Model No. 2100

August 1, 2001

Indications for Use:
The OSI Medical Dolphin Stand-Alone Pulse Oximeter and Accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The OSI Medical Dolphin Pulse Oximeter and Accessories are indicated for use with adult and pediatric patients who are well or poorly perfused in hospitals, hospital-type facilities and home environments.

The OSI Medical's sensor(s) are intended/indicated for use only with the OSI Medical Dolphin Stand-Alone Pulse Oximeter, and consist of the following:

Digital Dolphin Disposable Sensors intended for adults / pediatrics greater than 66.14 lbs. (30kg).
Digital Dolphin Reusable Sensors intended for adults / pediatrics greater than 66.14 lbs. (30kg).
Digital Dolphin 110 Extension Cable

The OSI Medical extension cable is intended/indicated for use only with the OSI Medical sensor(s) and the OSI Medical Dolphin Stand-Alone Pulse Oximeter.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number: K012533

Prescription Use ✓ OR over-the-counter Use_____
(Per 21 CFR 801.109)